REMARKS / ARGUMENTS

1. *Dayco / McKesson* Disclosure

In accordance the undersigned's current understanding of the obligations imposed by *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003) and *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897 (Fed. Cir. 2007), the following co-pending application(s) whose file history may contain material information are identified. In assessing the patentability of the pending claims, the Office is respectfully requested to review the file history of each the listed co-pending application(s), determine whether such co-pending application has "similar subject matter" and, if so, consider each Office Action, including each reference on which a rejection is based, and each paper submitted by applicant therein.

a. The subject matter of this application may be related to the subject matter of application serial no. 10/501,112, which is currently pending before Examiner Evanisco. This application is currently on Appeal.

b. The subject matter of this application may be related to the subject matter of application serial no. 11/663,115, which has not yet been assigned to an Examiner, has not yet been examined.

c. The subject matter of this application may be related to the subject matter of application serial no. 12/134,084, which is currently pending before Examiner Getzow, has not yet been examined.

2. Response to 06/09/2010 Non–Final Office Action

For the convenience of the Examiner and clarity of purpose, Assignee has reprinted the substance of the Office Action in ***9-point bolded and italicized font***. Assignee's arguments immediately follow in regular font.

Claims 1, 6, 8, 10-12, 16, and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Assignee continues to disagree with the Office's position. However, in an effort to

advance prosecution, Assignee has canceled claims 1, 6, 8, 10-12, 16, and 17. At least, because Assignee has traversed and continues to traverse this rejection, Assignee expressly reserves the right to present claims 1, 6, 8, 10-12, 16, and 17 in their previous and/or an amended form in the future. For example, should the Office continue to reject the remaining claims, Assignee expressly reserves the right to present claims 1, 6, 8, 10-12, 16, and 17 in a pre-appeal amendment and request the Board of Patent Appeals and Interferences overturn the present rejections thereof.

> ***As to claim 20, Ash discloses a method of controlling a blood pump, comprising:***
> ***receiving, in a controller, a flow signal from an implanted flow sensor, the flow signal indicative of an instantaneous flow waveform;***
> ***analyzing the flow waveform in both the time domain and frequency domain; and***
> ***outputting, from the controller, a control signal to control an implanted blood pump in response to the analysis of the flow waveform (col. 12 ll. 5-70).***

As an initial matter, Assignee does not accede to the Office's characterization of Ash as applied to the claims and Assignee respectfully reserves its right to present additional challenges that characterization in the future.

"A claim is anticipated only if each and every element as set forth in claim is found, either expressly or inherently described, in a single prior reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 631 (Fed. Cir. 1987). As the Court of Appeals for the Federal Circuit has held, "The test for anticipation is whether the claim reads on the product or process disclosed in the prior art, ***not on what that reference broadly teaches***." *SSIH Equip. S.A. v. United States Int'l Traded Comm'n*, 718 F.2d 365, 218 USPQ 678 (Fed. Cir. 1983) (emphasis added). Further, the law of anticipation requires that the prior art reference disclose each claim limitation ***arranged as in the claim***. See, e.g., *Brown v. 3M*, 265 F.3d 1349, 60 USPQ2d 1375 (Fed. Cir. 2001)("to anticipate, every element and limitation of the claimed invention must be

found in a single prior art reference, arranged as in the claim"); Karsten Mfg. Corp. v. Cleveland Golf 242 F.3d 1376, 1383 (Fed. Cir. 2001); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 47 USPQ2d 1225 (Fed. Cir. 1998)("a finding of anticipation requires that the publication describe all of the elements of the claims, arranged as in the patented device."); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)("These elements must be arranged as in the claim under review."). The Office may not establish anticipation by mere "substantial similarity" between the prior art disclosure and the arrangement of claim limitations. See *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556, 225 USPQ 253 (Fed. Cir. 1985). Rather, the Office may reject a claim as anticipated ***only*** when each and every claim limitation must be described identically in the single prior art reference. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

Claim 20 recites "receiving, in a controller, a flow signal from ***an implanted flow sensor***, the flow signal indicative of an instantaneous flow waveform; ... and outputting, from the controller, a control signal to control ***an implanted blood pump*** in response to the analysis of the flow waveform", emphasis added. Thus, claim 1 requires that both the flow sensor and the blood pump be implanted within a human body. For example, paragraph [0020] of the instant application explains (emphasis added):

> [0020] Turning to the figures, FIG. 1 illustrates a ventricular assist device (VAD) system 10 such as disclosed in U.S. Pat. No. 6,183,412, which is commonly assigned and incorporated herein by reference in its entirety. ***The VAD system 10 includes components designed for implantation within a human body and components external to the body. Implantable components include a rotary pump 12 and a flow sensor 14.*** The external components include a portable controller module 16, a clinical data acquisition system (CDAS) 18, and a patient home support system (PHSS) 20. The implanted components are connected to the controller module 16 via a percutaneous cable 22.

Thus, as explained in the specification, the flow sensor and blood pump of claim 20 are

implanted within a human body.

In contrast, Ash's delivery unit 109 (which includes a roller pump), sensor unit 110, and sensor block 116 are all external. Ash discloses absolutely no implanted pump or flow sensor. Thus, at the very least, Ash does not disclose each of the claim limitations, ***arranged as in the claim.*** For at least these reasons, Assignee respectfully submits that claim 20 is patentable over the disclosure and teaching of Ash. Reconsideration and withdrawal of this rejection is requested.

> ***As to claim 21, Ash discloses the method of claim 20, in which the analysis of the flow waveform determines a suction boundary condition (col. 12 ll. 5-70).***
> ***As to claim 22, Ash discloses the method of claim 21 where the boundary condition becomes control parameters for closed loop control (col. 12 ll. 5-70).***
> ***As to claim 23, Ash discloses the method of claim 21 where the boundary condition causes the control system to limit pump speed, and where upper boundary conditions do not allow the speed to be increased further while lower boundary conditions do not allow the speed to be decreased further (col. 12 ll. 5-70).***
> ***As to claim 24, Ash discloses the method of claim 21 where the boundary condition causes a predetermined decrease in speed then periodically attempts to return to the desired control mode at predetermined intervals (col. 12 ll. 5-70).***
> ***As to claim 25, Ash discloses the method of claim 20, in which the analysis of the flow waveform determines boundary conditions for suction, maximum power, maximum speed, minimum speed, minimum flow, change in flow peak-to-peak amplitude over change in pump speed, change in mean flow over change in pump speed, and change in pump power over change in pump speed (col. 12 ll. 5-70).***
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> ***The Applicant also does not teach an explicit definition of 'suction boundary condition', so this term is interpreted by the Examiner to include any boundary condition which affects the blood pump.***

Claim 21 recites "the analysis of the flow waveform determines a suction boundary condition." Claim 22 recites "the boundary condition becomes control parameters for closed loop control." Claim 23 recites "the boundary condition causes the control system to limit pump speed, and where upper boundary conditions do not allow the speed to be increased further while lower boundary conditions do not allow the speed to be decreased further." Claim 24 recites "the boundary condition causes a predetermined decrease in speed then periodically

attempts to return to the desired control mode at predetermined intervals." Claim 25 recites "in which the analysis of the flow waveform determines boundary conditions for suction, maximum power, maximum speed, minimum speed, minimum flow, change in flow peak-to-peak amplitude over change in pump speed, change in mean flow over change in pump speed, and change in pump power over change in pump speed". The claimed boundary conditions are explained, among other places, in paragraphs [0008] and [0034], which are reproduced below:

> [0008] Aspects of the present invention concern a physiologic control system and method for controlling a blood pump system such as a VAD system. The pump system includes, for example, a blood pump and a controller for controlling the pump. The system may further include a flow measurement device. Various control schemes are disclosed, including controlling the pump to achieve one or more of a desired speed, flow rate, or flow pulsatility. Additionally, various methods for determining maximal flow (the maximum flow that can be achieved for the patient while maintaining certain parameters or within certain boundaries) are disclosed.
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> [0034] If the desired flow for the patient cannot be achieved (e.g. a boundary condition is reached such as maximum speed, maximum power), then pump speed is not adjusted further. In other implementations, the control mode may be changed and the pump speed is reduced to achieve a desired peak-to-peak amplitude. In the control modes shown in FIG. 5, suction detection is either enabled or disabled. In other embodiments, varying levels of "ventricular unloading" are employed, assuming that the risk for suction is greatest with lower flow pulsatility.

Thus, one with ordinary skill in the art would understand the claimed boundary conditions to mean limits imposed on a control parameter, such as speed and/or power. For example, the controller will not attempt to increase speed beyond an upper boundary condition, or maximum speed.

In contrast, Assignee can find absolutely no discussion of anything remotely like the claimed boundary conditions, either in the portion cited or Ash as a whole. In fact, Ash does not even include the words maximum, minimum, speed, or suction. Thus, at the very least, it simply cannot be said that the claimed boundary conditions are described ***identically*** in Ash. For at

least these reasons, Assignee respectfully submits that claims 21-25 are patentable over the disclosure and teaching of Ash. Reconsideration and withdrawal of these rejections are requested.

> ***As to claim 26, Ash discloses the method of claim 20 where a fail-safe feature to switch to a Constant Speed mode is automatically enabled in the event the flow signal is lost, erroneous, or compromised (col. 12 ll. 49-55).***
> ***As to claim 27, Ash discloses the method of claim 26 where the quality of the flow signal is determined by the frequency domain analysis of the real-time flow waveform (col. 12 ll. 5-70).***
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> ***As to claim 12, Ash teaches automatically delivering defined amounts of fluid into the arterial line on present intervals if a patient reaches a 'dry weight', which can be considered an erroneous signal (col. 12 ll. 49-55).***

Claim 26 recites "a fail-safe feature to switch to a Constant Speed mode is automatically enabled in the event the flow signal is lost, erroneous, or compromised." Claim 27 recites "where the quality of the flow signal is determined by the frequency domain analysis of the real-time flow waveform." Paragraphs [0036], [0038], and [0040], among others, describe the constant speed mode, and how that mode is entered if the flow signal is of a poor quality, such as lost, erroneous, or otherwise compromised.

In contrast, the Office merely points to Ash's discussion of a "dry weight", and asserts that "can be considered an erroneous signal". Assignee can find no support for such an assertion. More specifically, Assignee can find no discussion of Ash's "dry weight" constituting "an erroneous signal". Assignee respectfully requests that the Office provide support for this assertion. In the absence of such support, it simply cannot be said that the fail-safe feature is described ***identically*** in Ash.

In fact, Ash's "dry weight" does not even appear to relate to a failure or unexpected, erroneous condition. For at least these reasons, Assignee respectfully submits that claims 26

and 27 are patentable over the disclosure and teaching of Ash. Reconsideration and withdrawal of these rejections are requested.

2. Conclusion

In responding to this Office Action, Assignee has presented only those arguments and made only those amendments that Assignee believes are warranted. Assignee has not, for example, responded to every factual or legal issue raised by the Office, and Assignee has not presented every argument supporting patentability that may be relevant. The decision not to address a factual or legal issue raised or to present a certain argument in support shall not be construed as Assignee's agreement with the Office on such issue or effect a waiver of Assignee's right to address such issues or make such arguments in the future.

Claims 20-31 are currently pending in this application. Assignee submits that each claim presented herein is patentable. A timely notice of allowance is respectfully requested.

Assignee thanks the Examiner for his/her consideration and effort on this file. If there are any questions or if additional information is needed, the Examiner is invited to telephone or email the undersigned.

Respectfully submitted,

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